



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,088	03/22/2004	Mary R. Flack	225011	1687
45733	7590	12/21/2004	EXAMINER	
LEYDIG, VOIT & MAYER, LTD. TWO PRUDENTIAL PLAZA SUITE 4900 CHICAGO, IL 60601			WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,088

Applicant(s)

FLACK ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-7 and 17-30 is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 1614

Claims 1-30 are presented for examination.

Applicants' preliminary amendment and information disclosure statement filed March 22, 2004 have been received and entered.

Reissue Applications

Allowable Subject Matter

Claims 5-7 and 17-30 are allowable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8-10, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Band et al., "Antiproliferative Effect of Gossypol and Its Optical Isomers on Human Reproductive Cancer Cell Lines", Gynecologic Oncology, 32, 273-277 (1989) or AG of PTO-1449.

Band et al. teach the antiproliferative effect of gossypol and its optical isomers on various human cell lines of reproductive and non-reproductive tissue origin. (See the abstract) Note the abstract states the (-)-gossypol was more potent than the (+)-gossypol and (±)-gossypol on the various cell lines. Band et al. discloses in the abstract, lines 5-8 that non-reproductive cancer cells were sensitive to (-)-gossypol, therefore, to treat cancer from a carcinoid tumor of neuroendocrine tissues located in the lung, pancreas, or gastrointestinal tract is clearly inherent by the administration of the instant compound. Clearly, the cited

Art Unit: 1614

reference anticipates the applicants' instant invention; therefore, the instant invention is unpatentable.

Claims 1-3, 8-10, 15 and 16 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Band et al. (AG) of the PTO-1449.

Band et al. were discussed above supra for the use of (-)-gossypol as an antiproliferative agent against various human cancer cells.

The instant invention differs from the cited reference in that the cited reference does not teach the blood concentration of the said compound disclosed in claims 4 and 11. However, the determination of the blood concentration of the said compound having optimum effectiveness against various cancers and cancer cells is well within the level of one having ordinary skill in

Art Unit: 1614

the art, and the artisan would have been motivated to determine an optimum blood concentration to get the maximum effectiveness of (-)-gossypol.

The instant invention differs from the cited reference in that the cited reference does not teach the dosage range of the said compound administered in various modes as disclosed in claims 12-14. However, to determine a dosage having optimum effectiveness against various cancers and cancer cells is well within the level of one having ordinary skill in the art, and the artisan would have been motivated to determine an optimum dosage to get the maximum effectiveness of (-)-gossypol.

Claims 4 and 11-14 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington

Application/Control Number: 10/806,088

Page 5

Art Unit: 1614

Primary Examiner
Art Unit 1614

K. Weddington
December 9, 2004